



European Haemophilia Consortium

EHC Roundtable of Stakeholders

Patient mobility: a solution for Haemophilia? 'Who/What should travel? Patients, clinicians, expertise and information on state of the art care''

Meeting Report

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Introduction

On 9 December 2009, the European Haemophilia Consortium (EHC) held a Round Table of stakeholders to debate the topic of "Patient mobility: a solution for Haemophilia? Who/What should travel? Patients, clinicians, expertise and information on state of the art care".

Over 30 participants representing clinicians, patients, the industry as well as decision makers from the Commission, Council of the EU and the European Parliament gathered in Brussels to address the different issues surrounding the topic of patient mobility. Special attention was paid to defining and assessing the criteria required to ensure access to best practice and on whether mobility of patients suffering from haemophilia can secure best possible treatment, or if other options are preferable.

Participants agreed that in the case of haemophilia patients, mobility of expertise should be privileged. They also agreed on the need to promote the development of sustainable centres of excellence, which plays a key role in improving the quality of treatment of patients with rare disease. Finally, there is a broad consensus on the need to harmonise safety standards for patients travelling across Europe.

Eighth Round Table of Stakeholders

This Eighth edition of the Round Tables organised by the EHC since 2007¹, addressed a topic that is of outmost importance to progress towards Comprehensive Haemophilia care in Europe.

The 8th edition of Round Tables focused on the topic of patients mobility



The EHC aims at facilitating this dialogue and promoting the need for progress on the elements related to care improvement and believes that Round Tables are the ideal platform to do so. With three Round Tables per year, the objective is to address different elements at each gathering. In doing so, they will give the opportunity to different stakeholders to contribute to the discussion and to help advance optimum Haemophilia care in Europe.

¹ For more information on the EHC roundtable series and other EHC advocacy activities, please go to www.ehc.eu.



Presentations

The meeting was opened by Brian O'Mahony, Member of the EHC Steering Committee and moderator of the session. Mr. O'Mahony gave a brief overview of what European Haemophilia Consortium is and the objective of the EHC Round Tables, along with a brief introduction on the subject of the 8th Round Table "Patient mobility: solution for Haemophilia? Who/What should travel? Patients, clinicians, expertise and information on state of the art care". Mrs. Marta Czerniawska, representative of the EHC European Office presented an overview of the issues around the Cross-border Healthcare Directive as a basis to the discussions of the Round Table.

Five speakers presented their views on all the factors related to patient mobility, and in particular tried to give an overview on how to secure quality and safety standards for haemophilia patients, how to facilitate mobility of expertise and best practice sharing for rare diseases, along with an overview of the Council perspective on the Cross-border Healthcare Directive and the Commission's view of the European Reference Networks. Their valuable contributions were a springboard for discussion surrounding these questions and helped shape the criteria required to better manage conditions such as Haemophilia.

United European standards for patient safety needed

Speaking on behalf of the Council of Europe, **Dr. Jean-Marc Spieser**, gave an overview of the work of the European Directorate for the Quality of Medicines & Healthcare (EDQM). The EDQM is involved in the harmonization and coordination of standardization, regulation & quality control of medicines, blood transfusion, organ transplantation, and pharmaceuticals. The EDQM is working on developing a guide for quality of blood and its components. Its aim is to make this guide a worldwide reference for quality of blood components, this can be achieved by working with countries to implement it as national standards. Australia and New Zealand have already transposed the standards in their national law and the World Health Organization (WHO) uses it as a reference guide. The organisation also works actively on donor management, to promote donations, make it safe for both the donor and the receiver and satisfy the demand of blood; the EDQM in inter alia, works on the optimal clinical use in blood components and plasma derivatives. In this regard, it advocates for the use of the "right product, at the right dose, to the right patient". Speaking on patient mobility, Dr. Spieser emphasised the importance of access of patients to the same level of quality of medicines, suitably controlled and safe by promoting common quality standards to make



Dr Jean-Marc Spieser, from the Council of Europe, stressed the need for united European standards for patient safety in cross-border and home healthcare.



sure the safest level is reached everywhere. To this end, The EDQM/Council of Europe is actively working with the European Commission, but also co-operating with international organisations such as the WHO and with countries such as the USA, Canada, Australia and hopefully soon Asia.

Participants asked Dr. Spieser whether he has close contacts with the biological unit of WHO to which his response was positive and that they work together on promoting common standards. Further, participants inquired on how they reach out to professionals to promote the clinical guidelines. Dr. Spieser pointed to one of the participants in this Round Table who helps to bring clinicians together and talking about the transposition of these guidelines in an adaptable way to the medical culture of the different countries.

Next steps on the Cross-border Healthcare Directive are uncertain

Mr. Enrique Esteller, representative of the Council of the European Union, gave an overview of the discussion taking place in the Council on the Cross-border Healthcare Directive and his personal views on this subject.

Mr. Esteller started off by explaining the reasons behind this Directive to find a balance between patients and Member States rights in the cross-border healthcare. Further, Mr. Esteller gave an overview of the issues that Member States agree and disagree. Member States broadly agree that patients should



Mr. Esteller provided an overview of the discussions in the Council of Ministers on the draft Cross-border Healthcare Directive

have the same rights to reimbursement, treatment, conditions to healthcare and avoid discrimination. As Member States differ on implementation of cross-border reality, instruments to manage inflow and outflow of patients are needed. In addition, clear distribution of responsibilities between Member State of affiliation and Member State of treatment needs to be put in place.

Furthermore, some of the issues on which Member States disagree are: the scope of the Directive meaning whether private and public health providers should be included and also whether only those that are contracted with the national social security systems should fall under the Directive or not. Finally, some Member States have problems with foreign pensioners living abroad and the question who should reimburse them create disparities in the Council.

Mr. Esteller commented on the possible next steps – one solution would be for the Commission to withdraw the proposal or modify it; alternatively, the Spanish



Presidency could decide to actively pursue a compromise on the current proposal.

After the presentation, a few participants reacted by asking whether changing the title of the Directive would help to find compromise as current title is too broad and misleading. Council representative agreed that title is misleading and expressed his view that there would be a Directive in some form as far as there are no new elements added to the current proposal and the idea remains to find a compromise on the current text.

Mobility of patients is a growing reality and an opportunity worth investing in

Dr. Magda Rosenmöller, Associate Professor at IESE Business School, gave a presentation on the future of the EU patients and opportunities through collaboration. Dr. Rosenmöller sees mobility of patients in Europe as an opportunity and a growing reality which Member States should treat as an investment in the future. Dr. Rosenmöller expressed her disappointment with the outcome of the Council's negotiations on the draft Cross-border Healthcare Directive. "People have the right to seek healthcare wherever needed. Countries should not block the Directive, they should instead readapt their systems" she said.



Dr. Magda Rosenmöller presented the advantages of mobility of patients and called Member States to treat it as investment in the future

Dr. Rosenmöller presented few examples on existing projects that provide opportunities for patients mobility through Member States cooperation. In particular, Hospital without borders is a joint project by France and Spain which looks at the application of labour law in hospitals. She also mentioned a number of projects which may bring patient closer to the cross-border reality such as: advanced medical websites, Telemedicine clinic in Sydney, Lonely Planet guide for patients website, etc.

Dr. Rosenmöller concluded her presentation by commenting on the current obstacles in the Council to the

Cross-border Healthcare Directive. She also added that differences of interests exist at national and regional level depending on who's responsible for healthcare and the healthcare services provision. In her views, reimbursement for cross-border healthcare should be done by the establishment of a European Clearing House. She added that Member States should treat the draft Directive as an opportunity and not a burden.



"Expertise should travel rather than patients themselves"

Speaking on behalf of the European Union of Medical Specialists (UEMS), Frédéric Destrebecq highlighted the importance of mobility of healthcare professionals to ensure quality and continuity of healthcare for patients seeking cross-border healthcare, in particular in the case of patients with rare disease. Over the last 50 years, the UEMS has been committed to developing standards in postgraduate training, continuing medical education and professional development. The association therefore calls for the establishment of European-wide standards for healthcare provision in order to guarantee the highest quality and safety of treatment in cross-border healthcare, and for the application of safety and quality standards to e-health and telemedicine uses.

If existing legislations set the basis for the free movement of healthcare professionals, the UEMS believes there is a need to address the specific issue of cross-border healthcare professionals within the scope of the patient's rights directive. Mr. Destrebecq further pointed out that the Council Recommendation on Rare Diseases adopted last June, clearly recognises that "where possible, expertise should travel rather than patients themselves".

In his views, what is really relevant for haemophilia patients when considering cross-border care is: the screening, cost and access to treatment, the duration and specificity of the treatment, the mobility of the information, as well as tackling disparities between Member States.

Mr. Frédéric Destrebecq, Acting CEO of UEMS, addressed the issue of professional mobility and its inclusion within the scope of the Cross-border Healthcare Directive





"Sustainability and funding of the ERN should be secured"

Mr. Antoni Montserrat presented the initiatives of the European Commission in the field of rare diseases. In particular, The Commission created a European Union Committee of Experts on Rare Diseases on 30 November with the objective to help establishing a methodology on the designation, accreditation and labelling of the future European Reference Networks (ERN). The role of the Centres of Expertise are crucial for patients with rare disease, and the most appropriate solution to ensure an adequate access to treatment in all Member States. Mr. Montserrat highlighted the importance of the Directive on Patients Rights in Cross-border Healthcare to ensure the long-term framework for the functionality of the European Reference Networks. The Directive clearly recognises the role of the ERN which encourage cooperation between Member States, sharing of best practices and knowledge, and facilitate mobility of expertise.



Mr. Antoni Montserrat from the European Commission, stressed the importance of the Directive on Cross-border Healthcare to ensure the long term framework for the functionality of the ERN

He also highlighted that the key criteria for rare diseases patients are: adequate access to diagnosis and high-quality and cost-effective healthcare for all patients in all Member States. In addition, Mr. Montserrat mentioned that the financial sustainability of the ERN will be addressed under the third EU Health Programme.

The Commission will continue assisting Member States in the implementation of national plans for rare diseases. So far, five Member States have adopted National Plans: France, Bulgaria, Portugal, Greece, Spain; Italy, Romania, Czech Republic are in the process of adopting their plans and eight Members States have structures in place (UK, Germany, the Netherlands, Cyprus, Luxembourg, Belgium, Hungary and Austria).



Discussions

During the debate, several questions arose on patient mobility for patients suffering of haemophilia. The existing disparities between Member States for the treatment of haemophilia patients were also tackled.

Another issue discussed was the management of national resources of governments. Participants agreed that Member States had the responsibility to reorganise their resources in order to put in place Centres of Expertise, and according to Mr. Brian O'Mahony this can be done with existing resources. Also one of the industry representatives commented that the Member States have cost concerns which may explain why they blocked the mobility of patients and information. It was suggested that smaller Member States could cooperate together to have few centres and set up a national coordination centre linked with an ERN.

Further, the problem of distribution of products for haemophilia patients was discussed where there are huge disparity between the number of units available per capita in Western Europe compared to those in Eastern Europe.

Another issue discussed was the real cost of patient mobility, which remains unclear. Enrique Esteller from the Council of the EU mentioned that Eurostat is in the process to conduct a survey to calculate the actual cost of patient mobility.

There was a general consensus that what is relevant for patients with rare disease is the mobility of expertise. Mr. Brian O'Mahony said "the concept of a comprehensive haemophilia care should travel rather than patients who need to be correctly diagnosed and feel secure in terms of the treatment, entering the hospital in their own country".

In addition Dr. Gunilla Brenning representing UEMS, pointed out that the cooperation between experts is the element which need to be emphasised.

Discussions gathered consensus on the mobility of expertise





Call for action

In this perspective, and echoing the Round Table debate, the EHC calls for:

- **Enhanced “knowledge” mobility** and use of new technologies to fill information gaps and thus reduce disparities of care across Europe
- **United European standards** to secure **patient safety** in cross border and home healthcare
- Implementation of a **concept of a comprehensive haemophilia care** in each European country
- **A trustful dialogue between experts** and **data sharing** to increase **cooperation between already existing Centers of Expertise** in the field of Haemophilia

Conclusion

The participants to the Roundtable agreed that the best preferable healthcare solution for patients suffering of haemophilia is mobility of expertise and the adoption of common European standards to guarantee the highest level of patient’s safety. In addition, the Roundtable called for increased cooperation between Centres of Expertise, and sharing of best practice in the field of rare disease.

The next EHC Round Table will take place in 2010 in Brussels. Further details would be available on the EHC website (www.ehc.eu) shortly.

For more information on the Round Tables and on the outcomes of this event, please contact the EHC EU representation office, tel: +32 (0)2 761 6627; email: info@ehc.eu.